I. Remarks

Claims 1-10 and 13-20 are currently pending.

As noted by the Examiner, the claims as amended no longer require an immunostimulatory tag listed in Table 1. As amended, independent claims 1, 7, 13, and 14 each contain a Markush group comprising 8 immunostimulatory factors. Applicants maintain their assertion that the search of the pending claims does not comprise such a serious burden that the restriction to a single immunostimulatory factor is required, particularly in light of the amendments to the claims. However, since the Examiner has made the restriction final, Applicants continue to reserve the right to petition from requirement for restriction under 37 C.F.R. §1.144.

Further with respect to the Markush group, Applicants note that, according to MPEP § 803.02, the Examiner must examine all members of the Markush group in the claims on the merits even if they are directed to independent and distinct inventions, if the examination can be made without serious burden. The Examiner has not established why a search of all members of the Markush group would be a serious burden. However, the current restriction does place a significant burden in terms of time and money on Applicants, which Applicants seek to avoid. If the Examiner feels that a telephone discussion with respect to the restriction would be helpful, Applicant's agent would welcome the opportunity to clarify their position.

Amendments to the claims:

Claims 1, 7, 13, 14, and 16 have been amended. Support for the amendment to claim 1 is found throughout the instant application and particularly at paragraphs [0008] and [0009]. Support for the amendment to claim 7 is found throughout the instant application and particularly at paragraphs [0008] and [0009]. Support for the amendment to claim 13 is found throughout the instant application and particularly at paragraphs [0070] and [0071]. Support for the amendment to claim 14 is found throughout the instant application and particularly at paragraphs [0070] and [0071]. Support for the amendment to claim 16 is found throughout the instant application and particularly at paragraphs [0071]. As such, these amendments do not add new matter. Their entry is respectfully requested.

Amendments to the specification:

Applicants respectfully requests entry of the amendment to the specification as provided in the section titled "Specification Amendments". This amendment does not add new matter. Support for this amendment is found in Request for Filing a Continuation or Division of an International Application filed for the instant application on November 5, 2001.

II. Priority

The Office has alleged that Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120. In accordance with 37 C.F.R. 1.78(a), the instant application properly claimed priority under 35 U.S.C. §120 to the international application no. PCT US/99/13800, which was co-pending at the time, through a specification amendment filed on November 5, 2001 within the Request for Filing a Continuation or Division of an International Application. Applicants have enclosed a copy of the Request filed on November 5, 2001 for the Office's convenience. Therefore, the required reference to the parent application was properly provided in accordance with 37 C.F.R. 1.78(a)

However, to further clarify this proper priority claim, Applicants have requested above the amendment of the instant specification to reflect the enclosed specification amendment. This amendment adds the reference to the applications to which the instant application claims priority as the first sentence of the specification.

III. Claim objections

Claims 17 and 18 stand objected to under 37 C.F.R. §1.75(c) as allegedly being of improper independent form for failing to further limit the subject matter of a previous claim. Specifically, claims 17 and 18 can allegedly comprise the entire scope of claim 7 as well as material not embraced by claim 7.

With this response, Applicants have amended claims 17 and 18 to further limit the subject matter of the claims from which they depend, which renders this claim objection moot. Applicants respectfully request its withdrawal.

IV. Claim rejections under 35 U.S.C. § 101

Claims 1-4, 7-9, and 13-18 stand rejected under 35 U.S.C. §101 because they are allegedly directed to non-statutory subject matter. In particular, the Office has alleged that they are drawn to various nucleic acids that occur in nature.

Claims 1-4, 7-9, and 13-18 have been amended to require that the claimed polynucleotides are "isolated" polynucleotides. Applicants respectfully request withdrawal of the rejection as these amendments render it moot.

V. Claim rejections under 35 U.S.C. § 112

Claims 1-10 and 13-20 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement because the claims contain subject matter which was

not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors at the time that the application was filed was in possession of the invention as claimed.

The Office interpretes the instant claims as embracing a genus of polynucleotides encoding any immunostimulatory factor that is differentially expressed in an antigen presenting cell as long as the polynucleotide also encodes PARC. The Office states that the instant application discloses 2137 decanucleotides that are differentially expressed in antigen presenting cells (APCs) and further urges that the instant application does not provide written description for the skilled artisan to recognize the specific structure of those 2137 decanucleotides for which the mRNA sequence is unknown. Therefore, the Office concludes that the skilled artisan would not recognize that Applicants were in possession of the instant invention at the time of filing. Applicants respectfully traverse.

The claims as amended require an immunostimulatory factor selected from the group consisting of PARC, TARC, MCP-4, MDC, ecalectin, MCP-2, and eotaxin 3. The instant specification fully describes these immunostimulatory factors throughout the specification and particularly at Table 1 where each factor is described by unique SAGE tag, SEQ ID. NO, description, and Accession number. The description identifies the known gene (or EST) that corresponds to the SAGE tag while the "Accession" column provides the accession number for gene or EST in public databases. See Table 1 at SEQ ID NO. 28 for PARC; at SEQ ID NO. 24 for TARC; at SEQ ID NOS. 7 and 263 for MCP-4; at SEQ ID NO. 23 for MDC; at SEQ ID NO. 258 for ecalectin; at SEQ ID NO. 580 for MCP-2; and at SEQ ID NO. 17 for eotaxin 3. As such, the skilled artisan would recognize that Applicants were in possession of the instant invention at the time of filing. Withdrawal of the rejection is respectfully requested.

VI. Claim rejections under 35 U.S.C. § 102

A) Claims 1-5, 7-10, and 13-20 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,891,432 (hereinafter referred to as Hoo) as evidenced by U.S. Patent No. 6,448,054 (hereinafter referred to as Hoo).

Specifically, the Office alleges that Hoo teaches expression vectors encoding immunomodulatory molecules, like PARC, expressed as membrane-bound fusion proteins (see page 10, third full paragraph, first line of the Office Action mailed February 24, 2004.) The Office concludes that, with these teachings, Hoo anticipates all elements of the instant invention. Applicants respectfully traverse. Hoo cannot and does not anticipate the instant claims because the claims as amended require that the encoded immunostimulatory factor is secreted.

Applicants have amended independent claims 1, 7, 13, and 14 to claim the embodiment of the instant invention wherein the encoded immunostimulatory factor is a secreted factor. These secreted factors function, for example, to recruit immune effector cells and/or to bind proteins present on the surface of antigen-presenting cells to stimulate the cells (see paragraphs [0058] and [0070], for example.)

In contrast, as noted above, Hoo requires a nucleic acid molecule that encodes for an immunomodulatory protein fused to a membrane attachment domain. Since the claims as amended require a secreted immunostimulatory factor, Hoo cannot and does not anticipate the invention as now claimed. Applicants therefore respectfully request removal of this rejection.

B) Claims 1, 4, 5, and 7-10 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Hieshima et al., (1997), J. Immunol. 159:1140.

The Office alleges that Hieshima teaches expression vectors encoding PARC and cells comprising these expression vectors, which thus anticipates all elements of the instant claims at issue. Applicants respectfully traverse.

With respect to claim 1 and those dependent therefrom, these claims no longer recite PARC as amended. Hieshima does not teach or suggest expression vectors encoding for TARC, MCP-4, MDC, ecalectin, MCP-2, or eotaxin 3. With respect to claim 7 and those dependent therefrom, Hieshima does not teach or suggest the element of the claimed invention wherein a second polynucleotide is present to modulate the expression of the first polynucleotide. Therefore, Hieshima does not teach all elements of claims 1, 4, 5, and 7-10. Absent all elements, Hieshima cannot and does not anticipate the invention as claimed. Applicants therefore respectfully request removal of this rejection.

C) Claims 1 and 6 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,474,796 (hereinafter referred to as Brennan).

The Office alleges that Brennan teaches an array of isolated oligonucleotides comprising every conceivable 10mer oligonucleotide sequence, which the Office alleges thus teaches every 10 nucleotide fragment present in a nucleic acid encoding PARC. The Office alleges that these fragments are potentially biologically active, which thus anticipates the instantly claimed invention. Applicants respectfully traverse.

Applicants have amended independent claim 1 to claim the embodiment of the instant invention wherein the encoded immunostimulatory factor is a secreted factor. These secreted factors function, for example, to recruit immune effector cells and/or to bind proteins present on the surface of antigen-presenting cells to stimulate the cells (see paragraphs [0058] and [0070], for example.) Brennan does not teach or suggest secreted immunostimulatory factors as required by the claims at issue. Therefore, Brennan cannot and does not anticipate the invention as claimed. Applicants therefore respectfully request removal of this rejection.